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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jaan Noolandi

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John E. Beck
Xerox Corporation
Xerox Square - 20A
Rochester, NY 14644

EXAMINER

BLIZZARD, CHRISTOPHER JAMES

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/740,209	Applicant(s) NOOLANDI ET AL.	
	Examiner CHRISTOPHER BLIZZARD	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/24/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/13/08 12/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/2006 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "Fresnel lens", "multiplexing circuit" and "sterilization mechanism" as cited in the claims must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 9, 19, 23 and 26 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Babev (6,601,581).

5. Regarding claims 1, 9 and 26, Babev discloses an apparatus for delivering a pharmaceutical product (18) comprising; a driver element (15) to generate acoustic energy in pulses (column 4, line 25) that are of a short duration and a low frequency, in a range of 18 kHz to 10,000 MHz (column 4, lines 19, 24), such that the droplet (10) of pharmaceutical product is output from a capillary wave (column 1, lines 22-27); an acoustic lens (13) to focus the acoustic energy generated by the driver (column 4, lines

55-56); and a delivery system (17) to maintain the pharmaceutical product in a position to receive the acoustic energy from the acoustic lens (fig. 2).

6. Regarding claim 2, Babev discloses a portable source (22) of electrical power coupled to the driver element (15) (fig. 2) (column 4, lines 62-66).

7. Regarding claim 19, Babev discloses a section (25) for insertion into a human orifice to increase amount of pharmaceutical product delivered to a patient (column 5, lines 3-5).

8. Regarding claim 23, Babev discloses the claimed method in claim 19.

9. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Humberstone (5,823,428).

10. Regarding claim 11, Humberstone discloses an apparatus for delivering a pharmaceutical product (91) (column 2, lines 51-53) comprising a driver element (72) to generate acoustic energy below 15 MHz (column 6, lines 9-11) and thereby generate a capillary wave (column 7, lines 18-20); and acoustic lens (53) to focus the acoustic energy generated by the driver (fig. 6e), a delivery system to maintain the pharmaceutical production in a position to receive the acoustic energy from the acoustic lens and cause ejection of a droplet of pharmaceutical production, the delivery system including a pressurization system that control the pressure of the pharmaceutical product (column 6, lines 29-32).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581)

Regarding claim 10, Babev discloses a range of droplet diameters to be .1 micron to several millimeters (column 1, lines 57-60). Thus, Babev has the claimed diameter.

14. Claim 3-6, 14-16 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Rawson (5,339,101).

15. Regarding claims 5, 6, and 14, Babev discloses an apparatus to output a pharmaceutical product (18) comprising; a portable energy supply (22), a transducer (15) coupled to the power supply (fig. 2) (column 4, lines 62-66) that output acoustic energy in a range of 18 kHz to 10,000 MHz (column 4, lines 19, 24), such that the droplet (10) of pharmaceutical product is output from a capillary wave (column 1, lines

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22-27); an acoustic lens (13) to focus the acoustic energy generated by the transducer (column 4, lines 55-56); and a delivery system (17) to maintain the reservoir (18,19) of pharmaceutical product, a distance from a top surface of a lens (13) and a surface of the reservoir is 50 microns (column 4, lines 45-47), the reservoir of pharmaceutical production to receive energy from the lens to cause ejection of a plurality of droplets a distance from the top surface of the lens (column 4, lines 51-56).

Babev does not disclose a plurality of lenses or a secondary driver element. Rawson et al. discloses a plurality of lenses (15) each attached to a driver unit (12) (fig. 2). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Babev with a plurality of lenses each attached to a driver element as taught by Rawson in order to provide the advantage of delivering more pharmaceutical at once.

16. Regarding claims 3, 4, 15, and 16, the modification of Babev by Rawson contains plastic Fresnel lens, taught by Rawson (column 2, line 1)

17. Regarding claim 22, the modification of Babev by Rawson above discloses the claimed limitations.

18. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Sweet (5,832,428).

19. Regarding claims 6 and 7, Babev does not disclose a second driver element, a second acoustic lens or a multiplexing circuit. Sweet discloses a second driver element (15) (fig. 3), a second lens (19) (fig. 3) wherein a multiplexing circuit (41) can direct RF energy from an energy source to any combination of driver elements (column 3, lines

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47-49). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Babev with a second lens and driver element attached to a multiplexing circuit as taught by Sweet in order to provide the advantage of delivering a more specific amount of pharmaceutical during any span of time.

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Hodson (6,012,454).

21. Regarding claim 13, Babev does not disclose a MEMS cover that protects the driver element from contamination when the drive is not outputting acoustic energy. Hodson et al. discloses an inhaler with a cover (47) that prevents contamination when not in use (column 15, lines 44-50). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Babev with a cover as taught by Hodson in order to provide the advantage of protecting the inner components from contamination.

22. Claims 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Elrod ("Nozzless droplet...").

23. Regarding claims 21, 24 and 25, Babev does not disclose the formation of capillary waves by relaxation of a principle mound. Elrod et al. teaches the formation of capillary waves from a principal mound (p. 3441, introduction, toward end of second paragraph) and the aerosol formed by the resulting capillary waves (p. 3444, Pulse Width: Ejection Stability and Droplet Diameter, first paragraph). Therefore it would have been obvious to one of ordinary skill at the time the invention was made to provide

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Babev's invention with the description of the formation of capillary waves as taught by Elrod et al. in order to provide the advantage of optimizing pharmaceutical output.

24. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Rawson (5,339,101) as applied to claim 14 above, and further in view of Ivri (6,205,999).

25. Regarding claim 17, the modification of Babev by Rawson does not disclose a circuit that detects air flow into a patient's lungs. Ivri teaches a flow sensor (24) (fig. 2) for detecting flow into a patient (column 7, lines 51-53) that couples to a transducer (26) to a circuit (column 7, lines 53-56). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Babev with a sensor as taught by Ivri in order to provide the advantage of preventing accidental dosing of pharmaceutical product.

26. Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Humberstone (5,823,428) in view of Blau (5372126)

27. Regarding claim 12, Humberstone does not disclose a sterilization mechanism. Blau discloses a sterilization mechanism that outputs ultraviolet energy for sterilization purposes (column 1, lines 48-50). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Humberstone with a sterilization mechanism as taught by Blau in order to provide the advantage of providing a safer means for providing pharmaceutical to a patient.

Response to Arguments

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28. Applicant's arguments with respect to claim 1-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bruce (6,740,530) a multi ejector system with fresnel lens, Asai (5,996,903) an atomizer using a vibrating array of lenses, and Takayama (5,912,679) an atomizer with reservoir controlling film level.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771